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Docket No.: 1752-0173PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hiroko YANAGA

Application No.: 10/552,000

Confirmation No.: 6374

Filed: October 4, 2005

Art Unit: 1632

For: METHOD OF PRODUCING
CHONDROCYTES FOR
TRANSPLANTATION

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on October 4, 2005, attached hereto is the International Preliminary Report on Patentability issued by the International Bureau on behalf of the International Searching Authority. Please make this document of record for the above-identified application.

If the Examiner has any questions or comments, please contact the undersigned at the offices of Birch, Stewart, Kolasch & Birch, LLP.

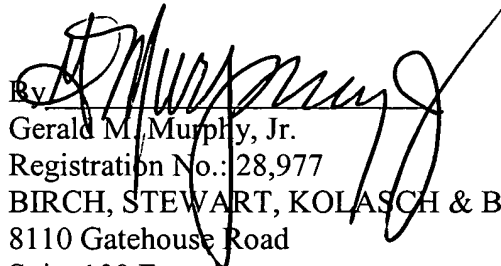
Application No.: 10/552,000

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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: April 11, 2006

Respectfully submitted,


By _____

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Attachment(s) **PCT/IB/338, PCT/IPEA 409**

PATENT COOPERATION TREATY

PCT/JP2004/005071

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NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

From the INTERNATIONAL BUREAU



To:

NARUSE, Katsuo
5th Floor, TKK Nishishinbashi Bldg.
11-5, Nishi-shinbashi 2-chome
Minato-ku, Tokyo 105-0003
JAPON

| | |
|--|--|
| Date of mailing (day/month/year) 09 March 2006 (09.03.2006) | IMPORTANT NOTIFICATION |
| Applicant's or agent's file reference NTK04-1597WO | |
| International application No. PCT/JP2004/005071 | International filing date (day/month/year) 08 April 2004 (08.04.2004) |
| Applicant YANAGA, Hiroko et al | |

1. Transmittal of the translation to the applicant.

- ☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).
- ☒ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

EP, KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

| | |
|---|---|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Masashi Honda |
| Facsimile No.+41 22 740 14 35 | Facsimile No.+41 22 338 70 10 |

Translation

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | | |
|--|---|---|-----------------------|
| Applicant's or agent's file reference NTK04-1597WO | | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
| International application No. PCT/JP2004/005071 | International filing date (day/month/year) 08.04.2004 | Priority date (day/month/year) 15.04.2003 | |
| International Patent Classification (IPC) or national classification and IPC | | | |
| Applicant YANAGA, Hiroko | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand | | Date of completion of this report | |
| Name and mailing address of the IPEA/JP | | Authorized officer | |
| Facsimile No. | | Telephone No. | |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/005071

Box No. 1 Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
 - ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☐ the international application as originally filed/furnished
 - ☒ the description:
 - pages 1-5, 8-12 as originally filed/furnished
 - pages* 6-7 received by this Authority on 02.11.2004
 - pages* _____ received by this Authority on _____
 - ☒ the claims:
 - nos. 1-6 as originally filed/furnished
 - nos.* _____ as amended (together with any statement) under Article 19
 - nos.* _____ received by this Authority on _____
 - nos.* _____ received by this Authority on _____
 - ☒ the drawings:
 - sheets 1/3-3/3 as originally filed/furnished
 - sheets* _____ received by this Authority on _____
 - sheets* _____ received by this Authority on _____
 - ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/005071

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|------------|-----|
| Novelty (N) | Claims | <u>1-6</u> | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | <u>1-6</u> | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | <u>1-6</u> | YES |
| | Claims | | NO |

2. Citations and explanations (Rule 70.7)

Document 1: WO 02/012451 A1 (Hiroko Yanaga), 14 February 2002

Document 2: Igaku no Ayumi, 2002, Vol. 200, No. 3, pages 258 to 259

Document 3: N Engl J Med, 1994, Vol. 331, No. 14, pages 889 to 895

Claims 1 to 6

The inventions set forth in claims 1 to 6 are novel and involve an inventive step in relation to documents 1 to 3 cited in the international search report.

Document 1 sets forth a method wherein a cartilage fragment is treated with trypsin, treated with type-II collagenase, and subjected to filtration, and the isolated cartilage cells are sown once or twice or more in a layered manner, and co-cultured with feeder cells to obtain human cartilage cell masses; and a cartilage treatment material comprising said cartilage cell masses and an enveloping material such as collagen.

Documents 2 and 3 set forth methods of single-layer cultivating cartilage cells isolated from human joint cartilage.

None of the documents mentioned above indicates that

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

cartilage cells are cultivated together with the perichondrium, and said feature would not be obvious to a person skilled in the art.